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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,690	03/12/2001	Stanley N. Cohen	STAN010 CON	1876

24353 7590 06/17/2003

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/17/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/804,690

Applicant(s)

COHEN ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-49 is/are pending in the application.
- 4a) Of the above claim(s) 28-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9,12,13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Seq. Alignment, Copy of claims

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I corresponding to claims 23-27 in Paper No. 15 is acknowledged. The traversal is on the ground(s) that searching of the different products of groups 1-VIII would not put a serious burden on the Examiner. This is not found persuasive because each of the different products in groups I-VIII has different chemical structures and different biological activities. Searching for all of the different inventions would put a serious burden on the Examiner for the reason of record. Note pages 3 and 4 of the previous Office action (Paper No.11)

The requirement is still deemed proper and is therefore made FINAL.

Claims 28-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

Claims 23-49 are pending and claims 23-27 are examined on merits.

Specification

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 24-50 has been renumbered 23-50.

Applicant states that all claims appear to be numbered incorrectly in the 1st sentence under REMARKS in the election (Paper No. 15). See the attached claims why the Office renumbered the claims; the originally filed claims skipped claim #2.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 6. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 says that applicant invention is an antibody that binds "specifically" to the recited protein but it is not clear what the property boundary of the claims is. The specification does not define what is meant by "specifically" as to the nature of the antibody being claimed by the claims. Is an antibody that binds to the protein disclosed in Fig. 4 (clone 257/CC2) at page 3103 (Maucuer et al, April 1995, Proc. Natl. Acad. Sci. USA, vol. 92, pages 3100-3104), within the metes and bounds of the applicant's invention? This rejection affects all the dependent claims

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection has two aspects. First, the claims are drawn to an antibody that binds a **genus of proteins called "a wild-type"** of TSG 101 protein. Second, the claims are also drawn to an antibody that binds to a **genus of proteins called "mammalian"** TSG101 protein.

The specification provides evidence for SEQ ID NO:2 and SEQ ID NO:4. Since the two categories of genus include a large number of unpredictable species such as other wild type protein from human due to allelic differences or from other species such as dogs and cats, possession of only two species is not seen as sufficient to reasonably convey possession of the entire genus. It is concluded that applicants adequately describes SEQ ID NO:2 and 4. This rejection affects all dependent claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Maucuer et al (April 1995, Proc. Natl. Acad. Sci. USA, vol. 92, pages 3100-3104) in

view of Campbell, A. (1986, Monoclonal antibody technology, Elsevier Science Publishers B.V., Chapter 1 only, pages 1-32) and Levinson et al (1994, Medical Microbiology & Immunology, 3rd edition pages 292 and 293 only).

The claims are interpreted as drawn to antibody capable of binding to instant SEQ ID NO:2 (mouse) and/or SEQ ID NO:4 (human). Maucuer et al teach 82 amino acid sequence CC2 protein, which is identical to amino acid #231 to 312 of instant SEQ ID NO:4 except two amino acids at position #237 and #275. Campbell, A. teaches that making monoclonal and polyclonal antibodies is a routine matter (see Table 1.1 at page 5) and one of ordinary skill in the art is motivated to make antibody for various reasons (see the last paragraph of page 29). Levinson et al teach that 5 amino acids could elicit and react with antibody. Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make an antibody and/or monoclonal antibody using an epitope from the primary reference (for example amino acids #240-265 of CC2 protein, note the attached sequence alignment) that are capable of specifically binding to the instant SEQ ID NO:2 and/or SEQ ID NO:4.

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maucuer et al in view of Campbell, A. and Levinson et al as applied to claim 23 above, and further in view of Harlow et al (1988, Antibodies, Contents at page iii-ix, 175, 321-3 only).

Claim 26 is drawn to a labeled antibody to TSG101 and claim 27 is drawn to a TSG101 antibody attached to a solid support. Harlow et al teach that labeling an antibody and attaching an antibody to a solid support is a routine matter.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
June 4, 2003

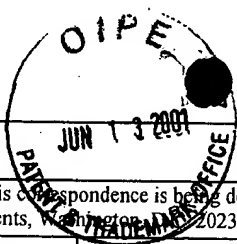

**MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800**

WHAT IS CLAIMED IS:

Rule 1.12b

1. An isolated nucleic acid encoding a TSG101 protein, or fragment of at least about 100 nt in length thereof, as other than an intact chromosome.
2. An isolated nucleic acid according to Claim 1, wherein said TSG101 protein is a mammalian protein.
3. An isolated nucleic acid according to Claim 3, wherein said nucleic acid is a cDNA.
4. An isolated nucleic acid according to Claim 3, wherein said TSG101 protein is mouse.
5. An isolated nucleic acid according to Claim 3, wherein said TSG101 protein is human.
6. An isolated nucleic acid according to Claim 6, wherein said sequence comprises an oncogenic mutation.
7. An isolated nucleic acid according to Claim 7, wherein said oncogenic mutation disrupts the coiled coil domain.
8. An expression cassette comprising a transcriptional initiation region functional in an expression host, a nucleic acid having a sequence of the isolated nucleic acid according to Claim 1 under the transcriptional regulation of said transcriptional initiation region, and a transcriptional termination region functional in said expression host.

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CERTIFICATE OF MAILING			
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.			
Typed or Printed Name		Barbara M. Weatherly	
Signature		<i>Barbara M. Weatherly</i>	
		Date	June 7, 2001
PRELIMINARY AMENDMENT Address to: Assistant Commissioner for Patents Washington, D.C. 20231		Attorney Docket	STAN010CON
		Confirmation No.	1876
		First Named Inventor	S.N. Cohen
		Application Number	09/804,690 / Conf. No. 1876
		Filing Date	March 12, 2001
		Group Art Unit	Unassigned
		Examiner Name	Unknown
		Title	MAMMALIAN TUMOR SUSCEPTIBILITY GENES AND THEIR USES

#4/A
Plunker
9/23/01

Sir:

Prior to examination of the application on the merits, please enter the amendments shown below.

I. AMENDMENTS

IN THE SPECIFICATION

On page 1, please replace the paragraph beginning on line 10 with the following paragraph:

This application is a continuation of U.S. Patent Application Serial No. 09/146,187, filed September 1, 1998, which is a divisional application of U.S. Patent Application Serial No. 08/977,818, filed November 25, 1997, now U.S. Patent No. 5,807,995, which is a divisional application of U.S. Patent Application Serial No. 08/670,274, filed June 13, 1993, now U.S. Patent No. 5,891,668, which is a continuation-in-part of application serial no. 08/585,758, filed January 12, 1996, now U.S. Patent No. 5,679,523, which claims priority to U.S. provisional patent application no. 60/006,856, filed November 16, 1995, the disclosures of which are herein incorporated by reference.

IN THE CLAIMS

Please cancel originally filed claims 1-23 without prejudice to renewal.

Please enter new claims 24-50, as shown below.

(New) An antibody that binds specifically to a wild-type mammalian TSG101 protein.

(New) The antibody of claim 24, wherein said antibody is a monoclonal antibody.

Handwritten notes: A 2 23 24, 724 6-1-03, 1.126, 24 25.